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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,935	02/15/2006	Kappei Tsukahara	082368-004400US	6397

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,935	TSUKAHARA ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

SUPPLMENTAL DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 8-6-08. Claims 1-8 are pending.

Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Rejection of claims 1-2, 4, and 7-8 under 35 U.S.C. 102 (a) is withdrawn in light of English translation of Japan 2002-339418.

b) Rejection of clams 1-8 under 35 U.S.C. 103 (a) is withdrawn in light of English translation of Japan 2002-339418.

c) Rejection of clams 1-8 under 35 U.S.C. 103 (a) is withdrawn in light of English translation of Japan 2002-339418.

New Grounds of Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-2 and 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6, and 12 of copending Application No. 11/409,453.

In the instant case, the claims (1-2 and 7-8) are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

U.S. Application No. 11/409,453 claims (1-2 and 7-8) are drawn to a method method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI, wherein a protein comprising the amino acid sequence of SEQ ID NO: 4 and a protein encoded by a DNA comprising the nucleotide sequence of SEQ ID NO: 3.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Application No. 11/409,453 recites the "method of screening for a compound having an antifungal activity". The species of the method of screening for a compound having an antifungal activity anticipate the genus claims of any method of screening for a compound having an antifungal activity.

Thus, claims 1-2 and 7-8 encompassing the method in the present application is obvious over claims 5-6, and 12 of U.S. Application No. 11/409,453.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukahara et al WO/2002/004626 Date January 17, 2002.

Claims 1-2 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test

sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis- inhibitory activity by binding assay with a membrane fraction expressing GWT1 protein to give inhibitors on transport of GPI anchor proteins. Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis-inhibitory activity, to give inhibitors on the transport of GPI anchor protein as antifungal agents. Tsukahara et al teach a DNA sequence (SEQ ID NO:1) that represents a gene of the invention (see STIC RESULTS). Therefore Tsukahara et al teach a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI (GPI); and selecting the test sample that decreases GlcN-(acyl)PI, wherein the GWT1 gene is a DNA comprising the nucleotide sequence of SEQ ID NO: 1.

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukahara et al WO/2002/004626 Date January 17, 2002 in view of Cardoso De Almeida WO/1995/022614 Date August 24, 1995.

Claims 1-8 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Tsukahara et al is relied upon as set forth supra. However Tsukahara et al does not teach thin-layer chromatography.

Cardoso De Almeida et al teach GPI extraction to recover the glycoinositolphospholipid by using a series of organic solvent/aqueous extractions which can be analyzed using standard processes of thin layer chromatography. Cordoso De Almeida et al teach GPI moieties produced by engineered organism that can be purified and analyzed according to standard procedures such as solvent selective extraction and fractionation by thin layer chromatography (see Example 8).

It would have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Tsukahara et al and to incorporate into the method a detection by thin-layer chromatography as taught by Cardoso De Almeida et al , because both Tsukahara et al and Cordoso De Almeida et al teach GPI proteins.

6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al US Patent 6,747,137 Date June 8, 2004 US Filing Date February 12, 1999 in view of Tsukahara et al Tsukahara et al WO/2002/004626 Date January 17, 2002, and Cardoso De Almeida et al WO/1995/022614 Date August 24, 1995.

Claims 1-8 are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI.

Weinstock et al teach a method of screening or testing for candidate anti-fungal compounds that impair Candida albicans comprising: a) providing fungal Candida albicans gene; b) providing one or more candidate compounds; c) contacting said gene with said one or more candidate compounds; and d) determining the ability of the candidate compound to inhibit gene activity. Weinstock et al teaches a method of screening test compounds for anti-fungal activity comprising providing a Candida albicans target sequence (see table 2 columns 587 and 588 contig3807) and contacting a test compound and determining binding of the test compound to said gene to determine whether said compound has anti-fungal activity (i.e. whether anti-fungal inhibits activity (see column 10 lines 28-45, column 20 lines 46-67 to column 21 lines 1-54).

Weinstock et al teach is relied upon as set forth supra. However Weinstock et al does not teach method for screening compounds having fungal cell wall synthesis-inhibitory activity specificically GWT1 gene and thin layer chromatography.

Tsukahara et al teach a method for screening compounds having fungal cell wall synthesis-inhibitory activity, to give inhibitors on the transport of GPI anchor protein as

antifungal agents. Tsukahara et al teach a DNA sequence (SEQ ID NO:1) that represents a gene of the invention (see STIC RESULTS).

Cardoso De Almeida et al teach GPI extraction to recover the glycoinositolphospholipid by using a series of organic solvent/aqueous extractions which can be analyzed using standard processes of thin layer chromatography. Cordoso De Almeida et al teach GPI moieties produced by engineered organism that can be purified and analyzed according to standard procedures such as solvent selective extraction and fractionation by thin layer chromatography (see Example 8).

It would have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Weinstock et al and to substitute the gene as taught by Tsukahra et al because both teach method for screening antifungal compounds. It would also have been prima facie obvious at the time the invention was made to have a method of screening for a compound having an antifungal activity according to Tsukahara et al and to incorporate into the method a detection by thin-layer chromatography as taught by Cardoso De Almeida et al , because both Tsukahara et al and Cordoso De Almeida et al teach GPI proteins.

Status of the Claims

7. No Claims are allowed.

Claims 1-8 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-0898. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. A. A./
Examiner, Art Unit 1645

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Mark Navarro/

Primary Examiner, Art Unit 1645